



genetic technologies



ASX ANNOUNCEMENT

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Genetic Technologies Announces Publication of Key Scientific Validation Results in Support of BREVAGenplus®

Melbourne, Australia, 21 December 2015: Molecular diagnostics company Genetic Technologies Limited (ASX: GTG; NASDAQ: GENE, “Company”) announced today the publication of a new independent study in support of the **BREVAGenplus®** breast cancer risk assessment test for Caucasian women. The results were published online first in **Cancer Epidemiology, Biomarkers & Prevention** on December 16, 2015. The paper, entitled “Breast cancer risk prediction based on clinical models and 77 independent risk-associated SNPs in women aged under 50 years: Australian Breast Cancer Family Registry,” can be accessed at: <http://cebp.aacrjournals.org/content/early/2015/12/16/1055-9965.EPI-15-0838.abstract>.

The study investigated the impact of 77 single nucleotide polymorphisms (SNPs) on the predictive accuracy of the Breast Cancer Risk Assessment Tool (BCRAT, also known as the Gail Model) and other commonly used breast cancer risk assessment models. The independent study was conducted under the supervision of Professor John Hopper and first authored by Dr. Gillian Dite from the Centre for Molecular Epidemiology at The University of Melbourne. The authors utilised the Australian Breast Cancer Family Registry to conduct a case-control study of 1,155 women aged between 35 and 50 years. All of these 77 SNPs are integrated into the Company’s BREVAGenplus breast cancer risk assessment test.

A key outcome from the study was demonstrating that including information on 77 SNPs associated with breast cancer risk improves the discriminatory accuracy of BCRAT (AUC improved by >20%), and extends that observation to other commonly used risk assessment models. The new risk prediction scores presented in the study, by combining the SNP-based score with the 5-year risk predictions from the models including BCRAT, are now the strongest known means available to physicians to assess the risk of a woman developing breast cancer. Guided by the BREVAGenplus test results, the physician is now better able to target and develop individualised breast cancer prevention and screening strategies for their patients.

“I’m extremely pleased with the results from this study as it firmly places the Company at the forefront of SNP-based risk assessment,” commented Mr. Eutillio Buccilli, Chief Executive Officer of Genetic Technologies Limited.

The Company recognises that scientific and clinical study data are key drivers for test adoption by physicians, the major breast health centres, and also for securing wider payer coverage. This new publication provides compelling scientific evidence indicating that improved risk assessment has the potential to substantially lower the impact of breast cancer. Genetic Technologies plans to deliver additional evidence demonstrating these potential health improvements in clinical studies, the first of which is scheduled to begin in Q2 FY16 with completion expected before the end of FY16. Two longer-term clinical trials are also expected to commence within the current financial year and are designed to run for up to two years. One of the longer term studies will be prospective in design, looking at patient outcomes, with the other being retrospective, assessing the impact of the test on MRI



screening rates. Taken together, these studies are designed to inform the medical community of the measureable improvements in health outcomes associated with BREVAGenplus testing.

FOR FURTHER INFORMATION PLEASE CONTACT

Mr. Eutilio Buccilli
Executive Director & Chief Executive Officer
Genetic Technologies Limited
+61 3 8412 7050

Candice Knoll (USA)
Blueprint Life Science Group
+1 (415) 375 3340, Ext. 4

About Genetic Technologies Limited

Genetic Technologies is a molecular diagnostics company that offers predictive testing and assessment tools to help physicians proactively manage women's health. The Company's lead product, BREVAGenplus®, is a clinically validated risk assessment test for non-hereditary breast cancer and is first in its class. BREVAGenplus® improves upon the predictive power of the first generation BREVAGen test and is designed to facilitate better informed decisions about breast cancer screening and preventive treatment plans. BREVAGenplus® expands the application of BREVAGen from Caucasian women to include African-Americans and Hispanics, and is directed towards women aged 35 years or above, who have not had breast cancer and have one or more risk factors for developing breast cancer.

The Company has successfully launched the first generation BREVAGen test across the U.S. via its U.S. subsidiary Phenogen Sciences Inc. and the addition of BREVAGenplus®, launched in October 2014, significantly expands the applicable market. The Company markets BREVAGenplus® to healthcare professionals in comprehensive breast health care and imaging centres, as well as to obstetricians/gynaecologists (OBGYNs) and breast cancer risk assessment specialists (such as breast surgeons).

For more information, please visit www.brevagenplus.com and www.phenogensciences.com.

Safe Harbor Statement

Any statements in this press release that relate to the Company's expectations are forward-looking statements, within the meaning of the [Private Securities Litigation Reform Act](#). The Private Securities Litigation Reform Act of 1995 (PSLRA) implemented several significant substantive changes affecting certain cases brought under the federal securities laws, including changes related to pleading, discovery, liability, class representation and awards fees. Since this information may involve risks and uncertainties and are subject to change at any time, the Company's actual results may differ materially from expected results. Additional risks associated with Genetic Technologies' business can be found in its periodic filings with the SEC.